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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/582,479

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Patrick John McAuliffe

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EXAMINER

BLIZZARD, CHRISTOPHER JAMES

ART UNIT

PAPER NUMBER

4185

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/582,479	Applicant(s) MCAULIFFE ET AL.	
	Examiner CHRISTOPHER BLIZZARD	Art Unit 4185	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/12/2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/12/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the anti-asphyxia valve must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. **Claims 1, 2, 4-6, 10, 11 and 13** are rejected under 35 U.S.C. 102(b) as being anticipated by **Choksi (US. 4,360,018)**.
2. **Regarding claim 1**, Choksi discloses a mask assembly comprising: a patient interface (42) (fig. 5) configured for connection to a patient in use, the patient interface being in communication with a source of gas pressurized (43) above atmospheric pressure; and a filter assembly (40) configured to receive gas exhaled by the patient in use, whereby the exhaled gas is vented to atmosphere (45) following passage through said filter assembly (column 4, lines 23-26).
3. **Regarding claim 2**, Choksi discloses a mask assembly comprising a connection joint (41) (fig. 5) defining a passage between the patient interface and the vent assembly.
4. **Regarding claim 4**, Choksi discloses a mask assembly wherein the connection joint (3) is an L-shaped joint in which the filter assembly (4) is positioned in use between the source of pressurized gas (14) and the L-shaped joint (fig. 1).
5. **Regarding claim 5**, Choksi discloses a mask assembly wherein the filter assembly (4) includes an inlet to receive the gas exhausted by the patient, a central chamber (33, 34), a filter (26) provided in the central chamber, and an outlet configured to release the exhausted gas following filtering (column 3, lines 49-57).
6. **Regarding claim 6**, Choksi discloses a mask assembly wherein the filter is made of a hydrophobic material (column 4, line 45).

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7. **Regarding claim 10**, Choksi disclose a mask assembly wherein the filter assembly (4) includes a filter (26).
8. **Regarding claim 11**, Choksi discloses a mask wherein the filter has a viral efficiency of greater than 99.999% (column 3, lines 60-61).
9. **Regarding claim 13**, Choksi discloses a mask wherein the filter assembly (40) is positioned in use between the source of pressurized gas (43) and the patient interface (42) (fig. 5).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. **Claims 3, 7-9 and 12** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Choksi (US. 4,360,018)**.

Regarding claim 3, Choksi discloses the claimed invention except for the connection joint comprising a T-shaped joint. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the connection joint as a T-shaped joint instead of a Y-shaped joint as taught by Choksi, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a forming edge in the heating portion or clamp. In re Dailey and Eilers, 149 USPQ 47 (1966).

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Regarding claim 7, Choksi discloses the mask assembly according to claim 5, but fails to disclose the central chamber being provided with a calibration cap including one or more openings.

However, applicant admitted prior art of a calibration cap (para [0025]) as being a commercially available part.

It would have been obvious to one of ordinary skill in the art to modify the invention of Choksi to include a calibration cap since it is known in the art for use with this type of device.

Regarding claim 8, Choksi discloses the mask assembly according to claim 7, but fails to disclose a calibration cap including a vent port in communication with the central chamber and a plug for said outlet.

However, applicant admitted prior art of a calibration cap (para [0025]) as being a commercially available part.

It would have been obvious to one of ordinary skill in the art to modify the invention of Choksi to include a calibration cap since it is known in the art for use with this type of device.

Regarding claim 9, Choksi discloses the mask assembly according to 1, but fails to disclose the mask assembly wherein the filter assembly includes an in-line vent positioned in use between the source of pressurized gas and the patient interface.

However, applicant admitted prior art of an in-line vent (para [0030]) as being a commercially available part.

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It would have been obvious to one of ordinary skill in the art to modify the invention of Choksi to include an in-line vent since it is a commercially available and more compact design for the embodiment of Choksi in figure 5.

Regarding claim 12, Choksi discloses the mask assembly according to claim 5, but fails to disclose the mask assembly wherein the filter has an impedance of not greater than about 2.0 cm water at about 60 liters per minute.

However, Choksi discloses a mask assembly wherein the filter has a low pressure drop of less than 0.3 inches of water at gas flow rates up to 12.5 L gas/minute.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the values of impedance taught by Choksi, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

12. **Claims 14-16** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Choksi (US. 4,360,018)** and **Gunaratnam (US. 7,185,652)**.

Regarding claim 14, Choksi fails to disclose a mask assembly further comprising an anti-asphyxia valve.

However, Gunaratnam et al. discloses a mask assembly further comprising an anti-asphyxia valve (abstract)

13. It would have been obvious to one of ordinary skill in the art to modify the invention of Choksi to include an anti-asphyxia valve as taught by Gunaratnam et al. since doing so would make the device safer to use.

Regarding claim 15, Choksi fails to disclose the mask assembly of claim 14, further comprising a filter cap provided to the filter assembly, wherein the anti-asphyxia valve is provided to the filter cap.

However, applicant admitted prior art of a calibration cap (para [0025]) as being a commercially available part.

Gunaratnam discloses an anti-asphyxia valve for use with a mask assembly (Abstract).

14. It would have been obvious to one of ordinary skill in the art to modify the invention of Choksi to include a calibration cap since it is known in the art for this type of device, and it would have been obvious to one of ordinary skill in the art to construct the device of Choksi with an anti-asphyxia valve as taught by Gunaratnam since doing so would make the device safer to use.

Regarding claim 16, Choksi disclose a mask assembly further comprising a vent (45), but fails to disclose a mask assembly wherein the anti-asphyxia valve is provided to the vent.

However, Gunaratnam disclose a mask assembly wherein a anti-asphyxia valve is provide to a vent (31) (column 2, lines 57-61).

15. It would have been obvious to one of ordinary skill in the art to modify the invention of Choksi to include an anti-asphyxia valve as taught by Gunaratnam et al. since doing so would make the device safer to use.

Conclusion

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are cited for disclosing related limitations of the applicant's claimed and disclosed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Blizzard whose telephone number is (571)-270-7138. The examiner can normally be reached on Monday-Thursday 7:30 AM - 6:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on (571) 272-4797.

1/15/09
/C. B./
Examiner, Art Unit 4185

/Terrell L McKinnon/
Supervisory Patent Examiner, Art Unit 4185